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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,603	11/24/2003	Ananda M. Chakrabarty	51282-00013	6398

7590 04/10/2008

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EXAMINER
YAO, LEI

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,603	CHAKRABARTY ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

The Amendment filed on 2/19/2008 in response to the previous Non-Final Office Action (11/16/2007) is acknowledged and has been entered.

Claims 3-4, 6, 8-19 and 21 were cancelled previously.

Claims 5 and 7 are cancelled currently in this amendment.

Claims 1, 2, and 20 are currently pending and are under consideration.

Rejections Withdrawn

The rejection of claims 1, 2, 7, and 20 rejected under 35 U.S.C. 112, first paragraph, does not reasonably provide enablement for the method of administering any mutated or truncated azurins of the amino acid sequences of SEQ ID NO: 1 for treating any condition comprising melanoma is withdrawn in view of the amendments to the claims.

Rejection Maintained- Double Patenting

Since no proper terminal disclaimer has been filed in the Office the pending claims (1, 2 and 20) **remain** rejected on the ground of nonstatutory obviousness-type **Double Patenting** as stated in the Office Action dated 11/6/2007 as the following:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. In reBerg, 140 F.3d, 1428, 46 USPQ2d 1226 (Fed. Cir. 1998): In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993): In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Patent No. 7084105:

1. Claims 1 and 20 **remain** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 7-12 of US patent No. 7084105 as the following:

Instant amended claims 1 and 20 are drawn to a method of treating a condition comprising administering to a patient azurin (SEQ ID NO: 1) to promote cell death, wherein the condition is human melanoma.

Claims 1-3, 5, and 7-12 of US Patent No. 7084105 are drawn to method of treating a cancer comprising melanoma comprising administering to a patient azurin, wherein the compound azurin modulate cell death.

Both sets of claim are directed to a method of treating a condition comprising melanoma by administering to a patient azurin or truncated azurin. The claims of US Patent 7084105 also include treating the disease with other cancer agent in combination and instant claims include promoting resistant cell death. Thus, the only difference between the two sets of claims is the scope of the claims. Because both set of the claims encompass a method of treating the same condition with the same materials the claim(s) is obvious over each other.

2. Claims 1 and 2 **remain** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 7-12 of US patent No. 7084105 in view of Yamada et al., (PNAS, vol 99, page 14098-14103, Oct. 2002, applicant's IDS A23).

Claim 1 of instant application is set forth above. Claim 2 is further drawn to claim 1 above, wherein azurin binds to tumor-suppressor protein p53 to promote cell death.

Claims 1-3, 5, and 7-12 of US Patent No. 7084105 are set forth above.

Claims US Patent No. 7084105 do not teach azurin binding to p53 to promote cell death,

Yamada et al., disclose azurin binding to tumor suppressor protein p53 and form a complex to induce cell death and regression of cancer (figure 5 and bridge page 14101-2).

It would have been *prima facie* obvious at the time the claimed invention was made to use the method described in claims of US Patent 7084105. One of ordinary skill in the art would have been motivated with reasonable expectation of success to combine the methods to treat a patient with a cancer by promoting cancer cell death by binding to p53 according to the teaching of claims US patent No. 7084105 because the claims of US patent have shown the method of using azurin to treat cancer and Yamada have shown that azurin binds to p53. Therefore, the claimed invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention as made, as evidenced by the claims of US Patent 7084105 in combination of Yamada's.

Application No. 11488693 (693'):

Claims 1 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22 of copending Application No.11488693 (693'). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1 and 20 of instant application are drawn to a method of treating a condition related to resistant to cell death comprising administering an effective amount of effective amount of azurin or mutated or truncated azurin, wherein resistance to cell death is human melanoma.

Claims 19-22 of 693' are drawn to method of treating patient suffering inappropriate angiogenesis comprising administering to a patient with a therapeutically effective amount of a cupredoxin, wherein suffering is melanoma.

The claims in the instant application and claims in application 693' are directed to a method of treating patient suffering from proliferative or cancer related disease comprising administering to a patient with a therapeutically effective amount of a cupredoxin comprising azurin. The differences among the

claim sets is that cancer related disease is resistant to cell death in the instant application and angiogenesis in the application 693', in which both are related with cancer comprising melanoma development and occurring and also instant claims encompass one species of cupredoxin, azurin, while the claims of application 693' are drawn to the genus of cupredoxin.

It would have been *prima facie* obvious at the time the claimed invention was made to use the one or more species of cupredoxin in method to treat the melanoma. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to use the method to treat a patient with melanoma because claims in application 693' has shown method of treating patient suffering angiogenesis comprising administering to a patient with a therapeutically effective amount of a cupredoxin, wherein suffering is melanoma.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application No. 11244105 ('105):

Claims 1 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 24 of copending Application No. 11244105 ('105). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1 and 20 of instant application are drawn to a method of treating a condition related to resistant to cell death comprising administering a patient an effective amount of azurin or mutated or truncated azurin, wherein the condition is melanoma.

Claim 24 of application'105 is drawn to method of treating patient with cancer with a complex of cargo compound and truncation of a full-length wild type of cupredoxin that comprise azurin

Both sets of claim are directed to a method of treating a condition comprising cancer or melanoma by administering to a patient a truncated cupredoxin comprising azurin or truncated azurin. The claims of application '105 also include treating cancer with the cupredoxin in a cargo compound to facilitate the entry to a cell. Thus, the only difference between the two sets of claims is the scope of the claims. Using a cargo compound to facilitate the therapeutic agent to entry to a cell is within the purviews of one skilled in the art. Because both set of the claims encompass a method of treating the same a condition, cancer with the same materials the claim(s) is obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The rejections would be obviated by a proper terminal disclaimer filed in the Office.

Conclusion:

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yamada et al., (PNAS, vol 99, page 14098-14103, provided in previous office action) teach that wild type of azurin exhibit cytotoxicity to melanoma tumor or mice with the tumor. Yamada et al., do not teach or suggest treating resistant to cell death by administering truncated or mutated form of cupredoxin or plastocyanin.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./
Examiner, Art Unit 1642

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/720,603	CHAKRABARTY ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	